Development and validation of a new pattern identification scale for Stomach Qi Deficiency

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ABSTRACT

Introduction: This study aimed to develop pattern identification scale for Stomach Qi Deficiency (SSQD) and investigated whether this questionnaire satisfied adequate reliability and validity.

Methods: To develop SSQD, we extracted major symptoms of Stomach Qi Deficiency (SQD) syndrome and requested an expert group to take part in a Delphi survey. The questionnaire was modified by the opinion of the expert group. For the analysis of reliability and validity and investigation of cut-off value, 30 participants who had dyspepsia and diagnosed as SQD and 30 healthy control participants were evaluated.

Results: Of the 13 questions in the SSQD, 1 question had negative effects on reliability and validity, therefore, it was excluded on further inspection. Overall Cronbach’s α coefficient of SSQD was 0.87. Construct validity was analyzed by factor analysis resulting 3 major factors. Using receiver operating characteristic curve analysis, the optimal cut-off value of SSQD was defined as 14, and its sensitivity and specificity were 93.33% and 86.67%, respectively. There were statistically significant positive correlation between SSQD and other dyspepsia severity scales.

Conclusions: The newly developed SSQD can provide fundamental reliability and validity as a specific pattern diagnosis questionnaire and can help diagnosing SQD. However, further studies will be needed to further confirm its specificity.
appropriate for diagnosing SQD was developed through agreement within the expert panels and literature searches. Subsequently, 30 participants in the SQD group and 30 participants in the healthy control group were tested to determine the reliability and validity of the developed questionnaire to confirm how much the questionnaire can explain and determine SQD. Additionally, the optimal cut-off value for diagnosis of SQD was deducted for objectification of pattern identification. Relationship of a newly developed questionnaire with previously developed and generally used dyspepsia-related questionnaires was analyzed for application in clinical use.

2. Methods

2.1. Fundamental development of pattern identification scale for Stomach Qi Deficiency pattern (SSSQD)

2.1.1. Selection of literature

For development of preliminary form for SSSQD, literature was searched to gather symptoms related to SQD. From previous related research articles and medical textbooks published from Korea and China, a total of 35 references with explanations on SQD were identified.

Ten Chinese textbooks related to diagnostics, pathology and internal medicine were selected with the exclusion of textbooks where the author and the publishing company were identical. A total of 257 Chinese articles were selected through the database website as China Knowledge Resource Integrated Database (CNKI) with search terms of ‘Stomach Qi Deficiency’, ‘shortage of Stomach Qi’ and ‘weak Stomach Qi’, of which 5 references with explanations of SQD were selected.

Among textbooks on diagnostics, pathology and internal medicine about Korean medicine written in Korean, 20 textbooks were selected explaining SQD. Korean research articles were searched through the database websites; the Korean studies Information Service System (KISS) and the Oriental Medicine Advanced Searching Integrated System (OASIS), with search terms of ‘Stomach Qi Deficiency’ and ‘Stomach Qi Deficiency pattern’. From our search results, 11 articles were selected, but none of these presented any symptoms or explanations realating to SQD. The whole selection process is shown below (Fig. 1).

![Flow chart of literature selection](image)

**Table 1**

<table>
<thead>
<tr>
<th>Question items</th>
<th>Importance (mean)</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>The upper abdomen is always uncomfortable and worse after meals.</td>
<td>4.462</td>
<td>1</td>
</tr>
<tr>
<td>Abdominal examination of a Korean medicine doctor (epigastric fullness, epigastric rigidity and sound of murmuring water)</td>
<td>3.846</td>
<td>2</td>
</tr>
<tr>
<td>No appetite for food</td>
<td>3.769</td>
<td>3</td>
</tr>
<tr>
<td>Pulse diagnosis of a Korean medicine doctor (fine and weak pulse)</td>
<td>3.769</td>
<td>4</td>
</tr>
<tr>
<td>Lethargy and weakness of body</td>
<td>3.692</td>
<td>5</td>
</tr>
<tr>
<td>Tongue diagnosis of a Korean medicine doctor (pale tongue with little coating)</td>
<td>3.615</td>
<td>6</td>
</tr>
<tr>
<td>Mild pain on the upper abdomen that is relieved by warmth</td>
<td>3.538</td>
<td>7</td>
</tr>
<tr>
<td>Time from onset</td>
<td>3.538</td>
<td>8</td>
</tr>
<tr>
<td>Frequent belching</td>
<td>3.231</td>
<td>9</td>
</tr>
<tr>
<td>Emotionally tired easily.</td>
<td>3.231</td>
<td>10</td>
</tr>
<tr>
<td>A sallow or pale face</td>
<td>3.154</td>
<td>11</td>
</tr>
<tr>
<td>BMI</td>
<td>3.153</td>
<td>12</td>
</tr>
<tr>
<td>Unable to distinguish the taste of foods</td>
<td>3.077</td>
<td>13</td>
</tr>
<tr>
<td>Loose stool</td>
<td>2.923</td>
<td>14</td>
</tr>
<tr>
<td>Sometimes nauseous or vomits</td>
<td>2.846</td>
<td>15</td>
</tr>
<tr>
<td>Frequent experience of acid reflux</td>
<td>2.462</td>
<td>16</td>
</tr>
<tr>
<td>Frequent hiccups</td>
<td>1.846</td>
<td>17</td>
</tr>
</tbody>
</table>

2.1.2. Selection of major symptoms

From each reference which listed the symptoms of SQD, major symptoms with high frequency were extracted. Fourteen major symptoms were extracted with exclusion of symptoms with a frequency of less than lower 30%. In addition to the extracted symptoms, 3 items of ‘patient’s Body Mass Index (BMI)’, ‘time from onset of symptoms’ and ‘abdominal examination (epigastric fullness, epigastric rigidity and sound of murmuring water)’ were considered clinically important to be included in the major symptoms and a total of 17 major symptoms were confirmed (Table 1).
2.1.3. Korean translation of symptoms

Three specialists on ancient Chinese and Chinese language, who majored in original classics and are currently full-time professors, were asked to review whether the Korean translation and expression of selected 17 major symptoms were appropriate. Korean translation was revised upon the review of above 3 specialists.

2.1.4. Evaluation on importance of major symptoms through delphi method

Above 17 items were evaluated in terms of importance. The expert panels composed of 18 professors at department of gastroenterology in Korean medicine, of whom 13 professors answered with a response rate of 72.22%.

The expert panels were surveyed on the importance of each major symptom on a scale of 5 points, and validity of symptoms and appropriateness of translation was also asked in an open question. The average importance of each symptom was calculated based on replies from the expert panels, and the result is shown in Table 1. In addition to the importance, opinions like ‘The pulse diagnosis shows need for criteria like right gate pulse.’ ‘Important point of pattern identification based on viscera and bowels seems to be tongue and pulse diagnosis.’ and ‘Performance of tongue, pulse, and abdominal examination depends on the skill of the performer.’ were received through open questions [16].

Upon the results from evaluation of importance, 4 items including ‘sometimes nauseous or vomits’, ‘loose stool’, ‘frequent experience of acid reflux’ and ‘frequent hiccup’ with average value if less than 3.0 were considered as not representative symptoms of SQD and therefore were excluded from SSQD.

In this study, two rounds of Delphi process were conducted. At the first round, expert panels evaluated their scores about the importance. At the second round, feedback process (showing average scores and one’s own scores in each item) was given and experts re-evaluated the importance and the consensus was reached. During whole process, the expert panels were kept anonymous.

2.1.5. Draft for SSQD

A total of 13 items were re-selected for SSQD. Based on these items, draft of SSQD was made up using a 5-point Likert scale (0: not at all, 1: not that much, 2: about medium, 3: frequently, and 4: very severe or all the time). Of these 13 items, 10 items were for respondents to answer directly to the questionnaire, while the rest of 3 items were for practitioner’s diagnosis for scores.

2.2. Validation for SSQD

2.2.1. Study design and inclusion/exclusion criteria

From July 2016 to November 2016 at Kyung Hee University Korean Medicine Hospital, a total of 60 participants whose age ranged from 19 to 74 were enrolled. Thirty participants who usually had dyspepsia and diagnosed as SQD with an agreement of two Korean medical doctors were enrolled into the SQD group. In addition, another 30 participants who did not have dyspepsia and were diagnosed as non-SQD were enrolled in the healthy control group. All participants were screened to ensure there was no existence of severe underlying diseases (e.g. malignant tumor, diseases of heart, lung, liver, kidney, etc.), malabsorption status or past history of neuropsychiatric diseases. Participants who were taking medications that can affect the gastrointestinal tract (antacid, H2 antagonist, prokinetics, antibiotics, NSAIDs, muscle relaxant, antidepressant, tranquilizer, etc.) were excluded.

All participants received a thorough and clear explanation of the purpose and method of the study from the researcher and voluntarily signed a consent form before participating in the study. This study followed the Helsinki declaration on ethical principles for medical research, and received a consent from the Institutional Review Board of Kyung Hee University Korean Medicine Hospital, (IRB No. KOMCIRB-160617-HR-030-02).

2.2.2. Demographics

Information collected on the sixty participants enrolled in this study included: sex, age, height, weight, body mass index (BMI), residence, past history and present illness, medication history, drinking habits and smoking.

2.2.3. Pattern identification diagnosis of SQD

Based on the inclusion and exclusion criteria, the participants were allocated into SQD group and the healthy control group.

Participants with dyspepsia were independently diagnosed by two Korean medicine doctors who were trained in department of gastroenterology, Kyung Hee University Korean Medicine Hospital and had clinical practice of more than three years. Those with SQD were enrolled in the SQD group. Likewise, participants with no dyspepsia were independently diagnosed by two doctors as not having SQD were enrolled in the healthy control group.

In this study, the gold standard of SQD diagnosis was considered only when the diagnosis of two doctors reached an agreement. This standard was the base for measuring sensitivity and specificity of the questionnaire. To enhance the objectivity of the pattern identification and keep the constant diagnosis, the two doctors who diagnosed for SQD were taught and trained enough on SQD prior to participation of the study.

2.2.4. Pattern identification scale for SQD (SSQD)

In this study, all participants filled out the draft version of SSQD developed prior to the study. For the 3 items in the questionnaire that require evaluation from practitioners (abdominal diagnosis, pulse diagnosis, and tongue diagnosis), one independent practitioners evaluated the each participants. Answers and data obtained from the participants were used to qualify the reliability and validity of SSQD, and received operating characteristic (ROC) curve was used to calculate the optimal cut-off value of the diagnosis.

2.2.5. Visual analogue scale (VAS) for dyspepsia

The participants were presented with a continued straight line from 0 mm to 100 mm with a standard of 0 as ‘no dyspepsia’ and 100 as ‘very severe dyspepsia’ and asked to draw a diagonal mark on the straight line where the discomfort of dyspepsia was felt.

2.2.6. Nepean dyspepsia index (NDI)

Nepean dyspepsia index is a scale used in evaluation for symptoms in the upper gastrointestinal tract developed by Talley [17], and translated in Korean [18]. This questionnaire has high test-retest reliability with qualification for concurrent validity, discriminant validity, internal consistency and construct validity [19]. NDI composes of table for symptom score, items for quality of life evaluation and weighted items. The table or symptom score evaluates 15 symptoms upon frequency, intensity and degree of discomfort. As of frequency, there are 5 ’ for how many days the symptom was present in the past 2 weeks. There are 6 ‘ in intensity and 5 ‘ in the severity of discomfort. In this study, the index for symptom score for evaluation of dyspepsia was used and the relationship between the index of NDI and SSQD was investigated.

2.2.7. Functional dyspepsia-related quality of life (FD-QoL)

This is a questionnaire designed to evaluate the overall quality of life related to functional dyspepsia with 4 domains and 21 items to be put on a 5-point Likert scale which was translated in Korean [20]. On the scale, 0 point is ‘not at all’, 1 point is ‘a little’, 2 points is ‘medium’, 3 points is ‘a lot’, and 4 points is ‘very much so’.

Questions are divided into 5 items for food intake, 4 items for vitality for life, 6 items for emotions and 6 items for social function. In this study, the relationship of this questionnaire with SSQD was investigated.
2.2.8. Statistical analyses

All data was presented as mean with standard deviation (SD) or number (%). Comparison of variables upon the general characteristics of the participants was performed by using independent t-test for continuous variable, or chi square test for categorical variables.

For calculation of internal validity of SSQD, Cronbach’s α coefficient was calculated from reliability analysis, and Cronbach’s α was compared to when each item was excluded. For qualification of construct validity of the questionnaire, principal component method from factor analysis was performed and factor rotation was performed via Varimax method. To investigate the clinical validity of the questionnaire, independent t-test compared whether there was any significant difference in the measurement value for each item in the SQD group and the healthy control group.

For deduction of the optimal cut-off value of diagnosis for SQD by using SSQD, received operating characteristic (ROC) curve was drawn to set the score where the Youden index becomes the greatest as the optimal cut-off point [21]. Area under curve (AUC) was calculated to evaluate the diagnostic function of the questionnaire.

Correlation analysis among the association indices used for dyspepsia (VAS, NDI and FD-QoL) was performed via spearman’s correlation analysis.

Calculation of ROC curve and AUC value was conducted by MedCalc 12.3.0 (MedCalc Software babv, Belgium) and other statistical analyses were performed via PASW statistics 18.0 (SPSS Inc., Chicago, IL, USA). Statistical testing was determined as significant for significance level performed on $P > 0.05$.

3. Results

3.1. General characteristics

Of the 60 participants, 29 were male and 31 were female. The average BMI of the participants was 21.25 ± 3.27 kg/m², and the average age was 38.97 ± 10.74 years old. The groups were not statistically significantly different in terms of age, BMI and sex (Table 2).

3.2. Reliability of SSQD

For the evaluation of internal reliability among the 13 items in SSQD, Cronbach’s α coefficient was calculated. The Cronbach’s α calculated from 60 participants was 0.866, with very high reliability. Cronbach’s α was also calculated for when each item is excluded, and comparison to the whole Cronbach’s α coefficient showed no great difference (Table 3). Items-Total correlation was greater than or equal to 0.3 in all the items except for the tenth item of BMI. Reliability test with exclusion of the tenth item resulted in a Cronbach’s α coefficient of 0.870, which is a little increase from the original.

3.3. Construct validity of SSQD

Thirteen items on SSQD from all participants were included in the factor analysis. Principal component analysis was conducted and factor rotation by Varimax method resulted in 4 main factors, the sum of eigenvalue of which was 9.086 explaining 69.897% of the questionnaire (Table 4). The seventh item as ‘a sallow or pale face’ showed repetition of factors with the loading of both the third and the fourth factor being greater than or equal to 0.500.

Principal component analysis without the tenth item as ‘BMI’ resulted in three factors and the sum of the eigenvalue of the factors were 7.791, explaining 64.929% of the questionnaire (Table 4). In this case, all items were deducted only in one factor, making the construct validity higher.

Number one factor was composed of 6 items including ‘time from onset’, ‘mild pain on the upper abdomen that is relieved by warmness’, ‘the upper abdomen is always uncomfortable and worse after meals’, ‘pulse diagnosis (fine and weak pulse)’, ‘tongue diagnosis (pale tongue with little coating)’ and ‘abdominal diagnosis (epigastric fullness, epigastric rigidity and sound of murmuring water)’, which were designated as the ‘characteristic factor of SQD’. Number two factor was composed of 3 items including ‘no appetite for food’, ‘not knowing taste of foods’ and ‘frequent belching’, which were designated as the ‘meal factor’, since they are related to food intake. Number three factor was composed of 3 items including ‘emotionally tired easily’, ‘lethargy and weakness of body’ and ‘a sallow or pale face’, which were designated as the ‘deficiency factor’, since they are bodily symptoms related to deficiency.

3.4. Clinical validity of SSQD

Thirteen items in the SSQD were completed out by participants allocated either to the SQD group or the healthy control group (Table 3). The tenth item, ‘BMI’ showed higher score in the SQD group than in the healthy control group, but with no statistical difference ($P = 0.901$). For the other 12 items, there were significant differences between the two groups, and it also showed the significant difference in the total sum ($P < 0.000$). Test for reliability and validity showed that the tenth item of BMI lowered the reliability and validity of the questionnaire, and therefore it was excluded in the analysis afterwards.

3.5. Optimal cut-off value for diagnosis of SQD

Using the previously defined golden standard about the diagnosis of SQD, ROC curve of SSQD was drawn and based this curve, the optimal cut-off value for diagnosis of SQD was deducted. ROC curve was calculated from 60 participants with exception of the score from the tenth item from the reliability and validity test. The optimal cut-off point which corresponded to maximum Youden index was calculated as 14 points, with the sensitivity of 93.33% (95% CI: 77.9–99.2), specificity of 86.67% (95% CI: 69.3–96.2) and Youden index of 0.800 points (Fig. 2). AUC value which determines the diagnostic function of the questionnaire was calculated to be 0.916 ($P < 0.01$).

3.6. Correlation of SSQD and other dyspepsia-related questionnaires

In this study, VAS, NDI and FD-QoL were compared to SSQD and a significant positive relationship of SSQD with all questionnaires was shown (Table 5). Particularly, in VAS and FD-QoL, high positive relationship was shown as 0.84 ($P < 0.000$) and 0.81 ($P < 0.000$) respectively, by spearman correlation coefficient.

4. Discussion

In this study, SSQD was developed with 12-items and high reliability was measured (Cronbach’s α = 0.870). The total variance explained using factor analysis was 64.929%, and all of items were related to the 3 main factors of SSQD. The optimal cut off value was 14 points through ROC curve analysis, and its sensitivity and specificity at the level were 93.33% and 86.67%, respectively. Taken together these
In Traditional medicine, the general process of pattern identification diagnostic method depends on the subjective expression of the patient and empirical decision of practitioners [22]. To overcome this subjectivity in diagnosis, there have been many studies for development of diagnostic tools to objectify and enhance the reproducibility of pattern identification diagnoses. For example, there is a representative method that evaluates patients with pattern identification tools like questionnaire makes inter-rater reliability higher and is more applicable in objectification and simplification viewpoint [23]. Therefore, this study also aimed to develop a pattern identification questionnaire appropriate for a simple and objective diagnosis of SQD that is widely seen in patients with gastrointestinal diseases.

For extraction of major symptoms of SQD, a lot of literature was

### Table 3

<table>
<thead>
<tr>
<th></th>
<th>SQD group (N = 30)</th>
<th>Healthy control group (N = 30)</th>
<th>P - values</th>
<th>Items/Total correlation</th>
<th>Cronbach’s α if items deleted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>2.37 ± 0.85</td>
<td>0.80 ± 0.55</td>
<td>0.000</td>
<td>0.70</td>
<td>0.848</td>
</tr>
<tr>
<td>Q2</td>
<td>1.07 ± 1.11</td>
<td>0.27 ± 0.45</td>
<td>0.001</td>
<td>0.41</td>
<td>0.863</td>
</tr>
<tr>
<td>Q3</td>
<td>2.43 ± 0.94</td>
<td>1.47 ± 0.97</td>
<td>0.000</td>
<td>0.54</td>
<td>0.857</td>
</tr>
<tr>
<td>Q4</td>
<td>1.60 ± 1.13</td>
<td>0.47 ± 0.68</td>
<td>0.000</td>
<td>0.57</td>
<td>0.855</td>
</tr>
<tr>
<td>Q5</td>
<td>2.07 ± 1.17</td>
<td>0.97 ± 0.85</td>
<td>0.000</td>
<td>0.51</td>
<td>0.858</td>
</tr>
<tr>
<td>Q6</td>
<td>2.53 ± 1.17</td>
<td>1.77 ± 0.97</td>
<td>0.004</td>
<td>0.46</td>
<td>0.861</td>
</tr>
<tr>
<td>Q7</td>
<td>1.67 ± 1.24</td>
<td>0.97 ± 0.93</td>
<td>0.011</td>
<td>0.50</td>
<td>0.859</td>
</tr>
<tr>
<td>Q8</td>
<td>0.97 ± 1.189</td>
<td>0.27 ± 0.58</td>
<td>0.006</td>
<td>0.47</td>
<td>0.860</td>
</tr>
<tr>
<td>Q9</td>
<td>3.83 ± 0.53</td>
<td>0.03 ± 0.18</td>
<td>0.000</td>
<td>0.76</td>
<td>0.845</td>
</tr>
<tr>
<td>Q10</td>
<td>2.07 ± 1.17</td>
<td>1.63 ± 0.72</td>
<td>0.091</td>
<td>0.27</td>
<td>0.870</td>
</tr>
<tr>
<td>Q11</td>
<td>2.30 ± 0.95</td>
<td>0.90 ± 0.48</td>
<td>0.000</td>
<td>0.67</td>
<td>0.850</td>
</tr>
<tr>
<td>Q12</td>
<td>2.17 ± 0.87</td>
<td>0.73 ± 0.58</td>
<td>0.000</td>
<td>0.71</td>
<td>0.848</td>
</tr>
<tr>
<td>Q13</td>
<td>2.03 ± 0.89</td>
<td>1.23 ± 0.73</td>
<td>0.000</td>
<td>0.47</td>
<td>0.861</td>
</tr>
<tr>
<td>Total score</td>
<td>27.10 ± 5.75</td>
<td>11.50 ± 3.21</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

SQD: Stomach qi deficiency.

### Table 5

<table>
<thead>
<tr>
<th>Dyspepsia Questionnaire</th>
<th>VAS</th>
<th>NDI</th>
<th>FD-QoL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correlation Coefficients</td>
<td>0.84</td>
<td>0.67</td>
<td>0.81</td>
</tr>
<tr>
<td>p-value</td>
<td>0.000</td>
<td>0.000</td>
<td>0.000</td>
</tr>
</tbody>
</table>

| VAS: Visual Analogue Scale for Dyspepsia; NDI: Nepean Dyspepsia Index; FD-QoL: Functional dyspepsia-related Quality of Life.

a Statistically significant correlation ($P < 0.01$).

### Fig. 2

Receiver operating characteristic curve of pattern identification scale for Stomach Qi Deficiency pattern.

The results, it is suggested that SSQD can be a useful and beneficial questionnaire for diagnosis of SQD.

In Traditional medicine, the general process of pattern identification diagnostic method depends on the subjective expression of the patient
searched resulting in a total of 35 references in Korean and Chinese. In this literature, there were 20 Korean and 15 Chinese references, however, there were no English references. All the Korean literature was in textbook format, and there were no research articles on SQD.

Based on the symptoms extracted from literature search, a survey was requested to the expert panels using a Delphi method. Symptoms with relatively high frequency in the literature search were not major symptoms.

The SSQD filled out by participants are composed of 13 items where 10 items are for the participants to check on points from 0 to 4 upon symptoms and 3 items evaluated by practitioners. The total sum of the score from each item is the final score, and the higher the final total score, the more severe the SQD. Among the whole items, ‘time from onset’ and ‘BMI’ were adopted as quantitative indexes reflecting chronic course. In addition, they were composed of 5-point scale for unity of composition of the questionnaire and scoring. ‘Time from onset’ was set as standard for scores via comments from experts through Delphi method and ‘BMI’ was subdivided into 5 categories upon the Asia-Pacific regional criteria for BMI [24]. On average, the time for participants to fill out the questionnaire was less than 5 min in this study.

Reliability test for SSQD through the Delphi method resulted in high degree of reliability. Cronbach’s $\alpha$ coefficient for the 13 items was relatively high with 0.866 and the coefficient showed no great difference when each item was excluded. Only for the tenth item as ‘BMI’, the items-total correlation coefficient was less than 0.3, which shows a little decreased consistency from what the other items aim to measure. Not only in reliability test, but also in factor analysis ‘BMI’ item had adverse effect on the construct validity. Additionally, it is the only item in clinical validity test with no significant difference between the SQD group and the healthy control group. Therefore, the tenth item as ‘BMI’ was finally excluded from the questionnaire. The reliability test performed with exclusion of the tenth item showed a little increase in the Cronbach’s $\alpha$ coefficient to 0.870, and result of factor analysis also showed that all the items were extracted to one factor.

This study chose to calculate the Cronbach’s $\alpha$ coefficient as a method of confirming internal consistency for evaluating reliability. When the Cronbach’s $\alpha$ coefficient was greater than or equal to 0.7, it was considered as acceptable tool, and a good tool when greater than or equal to 0.8 [25]. In this study, Cronbach’s $\alpha$ coefficient with exclusion of the tenth item was 0.870, which shows that the internal consistency of the questionnaire is excellent. However, since the reliability test was not performed and only internal consistency was conducted, further studies on stability testing through test-retest are needed.

Validity stands for the degree of how well the test measured the variable. Types of validity are content validity, construct validity, and criterion-related validity [26]. In this study, the construct validity of the questionnaire was tested by the factor analysis, and also clinical validity was analyzed. Factor analysis with exclusion of the tenth item resulted in 3 factors, each of which was designated as ‘characteristic factor of SQD’, ‘meal factor’, and ‘deficiency factor’. ‘Characteristic factor of SQD’ is composed of symptoms of discomfort in the upper abdomen like the ‘upper abdomen is always uncomfortable and worse after meals’ and ‘mild pain on the upper abdomen’ that is relieved by warmth’ with ‘time from onset’ accompanied by practitioner diagnosis of pulse, tongue and abdomen, making it hard to clearly nominate the factors, so it was designated as the ‘characteristic factor’. The variance explained by the 3 factors was 64.929%.

Clinical validity refers to the capacity of the questionnaire for differentiating clinically meaningful group [27], and, in this study, clinical validity to investigate the difference in the result of the 2 groups was measured. This also showed greater results in every item in the SQD group than the healthy control group with exception of the tenth item and the changes were statistically significant. For clinical application, clinical validity test for not only SQD patients with dyspepsia, but also for patients who have specific disease such as functional dyspepsia patients is additionally needed.

For the cut-off point, the decision on the SQD as diagnosed by two practitioners was considered as the golden standard, and this also lead to the ROC curve. ROC curve is a graph with the false-positive rate (1 – specificity) on the X-axis and sensitivity (1 – false-negative rate) on the Y-axis upon the diagnostic cut-off value. Measuring the area under the ROC curve is the AUC that tells the diagnostic function of the test [28]. Analysis of the ROC curve as a result of questionnaire answered by 60 participants, the optimal cut-off value of the questionnaire was calculated as 14 points. Upon the sum of scores in the questionnaire being greater than 14, the sensitivity was 93.33% and specificity was 86.67%, with AUC value of 0.916, which tells that it is an accurate test for differentiating SQD. However, since this explorative study was performed on 60 participants, the sensitivity, specificity and AUC may have been calculated a little higher, and further studies with a large sample of participants should be needed. For accurate evaluation of the diagnostic capacity, Cohen’s kappa coefficient analysis can be considered and used to evaluate the diagnostic consistency with the golden standard.

From correlation analysis of the SSQD with other dyspepsia-related questionnaires such as VAS, NDI and FD-QoL, all questionnaires showed positive correlation with SSQD. Particularly, the correlation coefficient in the VAS and FD-Qol was high, since these questionnaires not only reflect gastrointestinal symptoms but also general conditions of the body. This can be the representative characteristics of the pattern identification that evaluates the overall condition of patients.

In this study, the participants who complained of obvious dyspeptic symptoms were selected as candidates for SQD. Then, the participants with obvious dyspepsia were screened by two independent Korean medicine doctors if they also had SQD or not. In case the each diagnosis of positive SQD by 2 Korean medicine doctors reached an agreement, that participant was finally diagnosed as SQD and enrolled to SQD group. Therefore, participants with dyspepsia who were not diagnosed as SQD were not enrolled in this study. Likewise, the participants with no dyspepsia who were diagnosed as negative SQD by two independent Korean medicine doctors were enrolled as healthy control group.

SQD is a mixture of related symptoms and signs like other pattern identifications in traditional Korean medicine. Therefore, there are major or minor symptoms and signs among the each component of SQD diagnosis. Clinically, lowered function of digestion such as meal-related symptoms (no appetite, belching, etc.) and coldness of upper abdomen were considered to be the major symptoms and signs in SQD patients. These can be the differential points compared with other ‘Qi deficiency’ pattern identification. As a results, ‘mild pain on the upper abdomen that is relieved by warmth’, ‘the upper abdomen is always uncomfortable and worse after meals’, ‘no appetite for food’, ‘not knowing taste of foods’, ‘frequent belching’ and ‘abdominal diagnosis’ were selected as diagnostic items in SQD.

Since the participants in the SQD group were selected from dyspepsia patients, correlation analysis of SSQD and other questionnaires used indices related to digestion like VAS, NDI, and FD-QoL. However, since ‘deficiency factor’ was analyzed, further studies should be investigated on the correlation with tiredness or other deficiency-related indices for better understanding and interpretation of the SSQD. Nevertheless, the SSQD might be a useful diagnostic tool for objective and quantitative measurement in the clinical study.

5. Conclusions

For developing SSQD, literature search, extraction of major symptoms, evaluation of important of major symptoms through Delphi method was conducted. Cronbach’s $\alpha$ coefficient of the SSQD was 0.870 and there were 3 major factors which describe 64.929% of the questionnaire derived by principal component method from factor analysis. ROC curve was drawn to deduct the optimal cut off value of scale, and it was calculated as 14 points, with the sensitivity of 93.33%, specificity of 86.67%. Through this study, SSQD which can be a beneficial tool to
make decision on SQD was developed and it showed high reliability and validity. Application of SSQD is expected to accommodate elevation of diagnostic rate of SQD in clinical situation and also, quantitative evaluation of SQD is possible. Further study is needed for deliberate validation of cut-off value, and confirmation of disease specificity of SSQD.

Conflicts of interest

The authors declare that there is no conflict of interest regarding the publication of this article.

Author’s contribution

Jaehyung Lee designed the study and contributed to the editing of the paper. Jaehyung Lee and Jae-woo Park contributed equally as first authors. All authors read and approved the final paper.

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Appendix A

See Table A1

Table A1

Revised version of pattern identification scale for Stomach Qi Deficiency (SSQD).

<table>
<thead>
<tr>
<th>Item</th>
<th>Question</th>
<th>Not at all (0)</th>
<th>Not that much (1)</th>
<th>About medium (2)</th>
<th>Frequently (3)</th>
<th>Very severe or all the time (4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The upper abdomen is always uncomfortable and worse after meals.</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>2</td>
<td>No appetite for food.</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>3</td>
<td>Lethargy and weakness of body.</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>4</td>
<td>Mild pain on the upper abdomen that is relieved by warmness</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>5</td>
<td>Frequent belching</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>6</td>
<td>Emotionally tired easily.</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>7</td>
<td>A sallow or pale face</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>8</td>
<td>Unable to distinguish the taste of foods</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
<td>![ ]</td>
</tr>
<tr>
<td>9</td>
<td>When did the symptom start? Date of onset:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Items below are filled out upon diagnosis of a Korean medicine doctor.

<table>
<thead>
<tr>
<th>Time from onset</th>
<th>Less than one week</th>
<th>More than or equal to one week and less than one month</th>
<th>More than or equal to one month and less than three months</th>
<th>More than or equal to three months and less than six months</th>
<th>More than or equal to six months</th>
</tr>
</thead>
</table>

1 Existence and severity of epigastric fullness, epigastric rigidity, and sound of murmuring water upon abdominal diagnosis of Korean medicine doctor.

2 Korean medicine doctor’s evaluation on pulse as fine and weak.

3 Korean medicine doctor’s evaluation of the tongue as pale tongue with little coating.

References


